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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,167	11/07/2000	Maurice Maloney	9369-161	8170

1059 7590 08/29/2002

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/29/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,167

Applicant(s)

MALONEY ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 are cancelled and Claim 18-33 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Preliminary amendment filed 13 6 March 6 2000 (Paper 15) prior to patent examination as to cancellation of Claims 1-17 and addition of new Claims 29-33 and preliminary amendment filed 2 August 2002 have been entered.

Claims 18-33 are pending and examined in this Office action.

Drawing

The drawing (Figures 1-18) filed 7 November 2000 is acceptable subject to correction of the informalities indicated on the attached "Notice of Draftperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

The following is the information on how to effect drawing changes.

1. New corrected drawings must be filed with the changes incorporated therein.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948. All

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changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

In addition, Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in abandonment of the application.

Objection to Specification

The disclosure is objected to because of the following informalities:

In page 8, line 5, the term "HPR" should be spelled out for the first instance of use. See also page 19, line 23, 'CaMV'.

Corresponding correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite in the recitation "the ligand is a polypeptide and said recombinant polypeptide is prepared as a fusion protein with said ligand and wherein the ligand is not a

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protein...” because the limitation “the ligand is not protein” is contradictory to the preceding recitations “the ligand is a polypeptide” and “...is prepared as fusion protein with said ligand”. Note that a fusion protein refers to multiple portions of polypeptides are linked via peptide bond(s). Thus, the said ligand which is a part of the fusion protein should be a polypeptide in nature. See also Claim 23. The dependent claims are also rejected as they do not clarify this ambiguity.

Claim 24 recites the “according to claim 23 wherein said ligand is antibody”. There is insufficient antecedent basis for this recitation in the claim since the said ligand in Claim 23 is recited as a non-proteinous molecule whereas the antibody as recited in the claim is a type of protein molecule.

Claim 25 recites “disruption of the cell’s integrity”. It is not apparent as to whether or not the said disruption regards chemical or physical distraction.

Claim 26 is unclear as to the recitation “covalent attached to a target molecule” because “covalently attached to” can refer to either (i) covalently linking to side chain of the target polypeptide molecule or (ii) forming a peptide bond linkage between ligand molecule and the target molecule.

Claim 28 is indefinite in the recitation “...wherein the ligand is not a protein that is normally associated with oil bodies”, in which the limitation “the ligand is not a protein” is contradictory to the preceding recitation in the same claim “the ligand molecule and target molecules are covalently attached as a recombinant fusion protein” wherein the fusion protein should refer to multiple polypeptide moieties or full-length-chains are linked via peptide bonds.

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The recitation appears to regard the fusion polypeptide instead of conjugation between a side chain of the polypeptide and a ligand molecule.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 18-20, 22, 24, 26, 27, 29 and 30-33 are rejected under 35 U.S.C. 102 (a) as being anticipated by Moloney, M. (US Pat. No. 5650554).

Moloney teaches a method for the separation/purification of recombinant proteins (target molecule) from host cell by partitioning of oil body fraction and subsequent isolating said oil bodies associated with the recombinant protein (see Column 5, lines 29-32, column 6, lines 19-30, and column 8, lines 13-19), as applied to Claim 18 and 29 of the instant application.

Moloney teaches the recombinant (fusion) polypeptide binds a ligand, which is an antibody against the oil body protein (see column 19, lines 59-61, and Example 7), as applied to Claims 19, 24, 30 and 31 of the instant application.

Moloney teaches the separation of the target molecule comprising: a DNA sequence encoding the target (recombinant) polypeptide (see column 5, lines 40-41) and the other DNA sequence encoding the oil body protein which acts as a ligand (see column 5, lines 40-41); thus, the target polypeptide is able to associate with the said oil body (ligand) allowing for oil body-mediated the polypeptide separation, as applied to Claim 22 of the instant application.

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association of the target polypeptide with the oil body (see column 14, lines 54-56, column 8, lines 50-54, and Claim 1, item 2), as applied to Claims 26, 27 and 33 of the instant application.

Further, Moloney teaches a mean of purifying recombinant polypeptides from host cells where the polypeptides are expressed (see column 8, lines 13-19), as applied to Claim 32 of the instant application.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 18-20 and 29-33 are rejected under the judicially created doctrine of the obviousness-type double patenting over Claims 1-4, 7, 13, 14 and 21 of US patent No. 5856452. Although the conflicting claims are not identical, they are not patentably distinct from each other.

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Claim 3); the disclosure is identical to the recitation “ a protein ligand” of Claims 29 and 32 of the instant application.

Claims 2 and Claim 4 taken with Claim 7 of US Pat. No. 856452. disclose the subject matter of Claim 30 and 31 of the instant application. Claims 30 and 31 of the instant application sets forth the protein ligand is an antibody. Accordingly, US Pat No. 856452 discloses that the ligand is an antibody and binds to both the oil bodies and target molecule.

Claim 33 of the instant application sets forth that the target is a protein and the protein ligand molecule is prepare as a fusion protein with the polypeptide target molecule. Accordingly, US Pat. No. 856452 discloses the target molecule is polypeptide (see Claim 21), ligand molecule is a protein (see Claims 2 and 3) and a fusion protein between polypeptide ligand and protein target (see Claims 13 and 14).

Also, Claims 1 –3 of US Pat. No. 5856452 disclose the identical subject matter as Claims 18-20 of the instant application except the scope of claims differing. Claims 1 –3 of US Pat. No. 5856452 sets forth a method of separation of a target molecule from a mixture employing oil bodies as affinity matrices for selective non-covalent binding of desired target molecules.

Although Claims 1 –3 do not explicitly disclose that the isolation of a recombinant polypeptide

(a target molecule). US Pat No. 58566452 teaches that the target encompasses

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



SWL



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

August 28, 2002

Attachment for PTO-948 (Rev. 03/01, or earlier)

6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.